

**Conclusions:** Our 3-y FU data reinforce the concept that TAVI should be avoided when the native annulus perimeter is  $> 8.5$  cm. In this context the larger CoreValve available (31 mm) cannot be used as oversizing prosthesis. To the contrary when an oversizing valve prosthesis can be used acceptable results are achieved. In this setting of pts TAVI showed no death, and good clinical outcomes that were sustained at 3-y FU.

## TCT-756

### Incidence, Predictors, and Prognostic Impact of Late Bleeding ( $\geq 30$ days) Complications after Transcatheter Aortic Valve Replacement (TAVR)

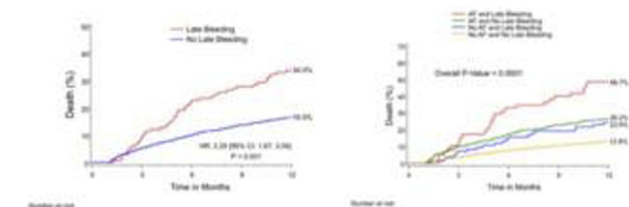
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**Background:** The incidence and prognostic impact of late bleeding complications (LBC) after TAVR are unknown. We sought to identify the incidence, predictors, and prognostic impact of LBC ( $\geq 30$  days) after TAVR.

**Methods:** Clinical and echocardiographic outcomes of patients who underwent TAVR within the randomized cohorts and continued access registries in the PARTNER trial were analyzed after stratifying by the occurrence of LBC. Predictors of LBC and its association with 30-day to 1-year mortality were assessed.

**Results:** Among 2,401 patients who underwent TAVR and survived to 30 days, LBC occurred in 142 (5.9%) at median time of 132 [71, 230] days after the index procedure. Gastrointestinal (n=58; 40.8%), neurologic (n=22; 15.5%), and traumatic falls (n=11; 7.8%) were identified as the most frequent types of LBC. Independent predictors of major LBC were the presence of atrial fibrillation or flutter (AF) at baseline or 30 days, the presence of moderate/severe paravalvular leak (PVL) at 30 days, the presence of low hemoglobin at baseline, and greater left ventricular mass at 30 days. LBC was identified as a strong independent predictor of mortality between 30 days and 1 year (adjusted HR 3.91, 95% CI [2.67, 5.71],  $p < 0.001$ ). The presence of AF, especially when LBCs occurred, was associated with a poor prognosis and high rate of mortality.

**Conclusions:** LBC after TAVR were frequent and associated with increased mortality. A better-individualized and risk-adjusted antithrombotic therapy after TAVR is urgently needed in this high-risk population.



## TCT-757

### Long-Term Results Following Transcatheter Aortic Valve Implantation

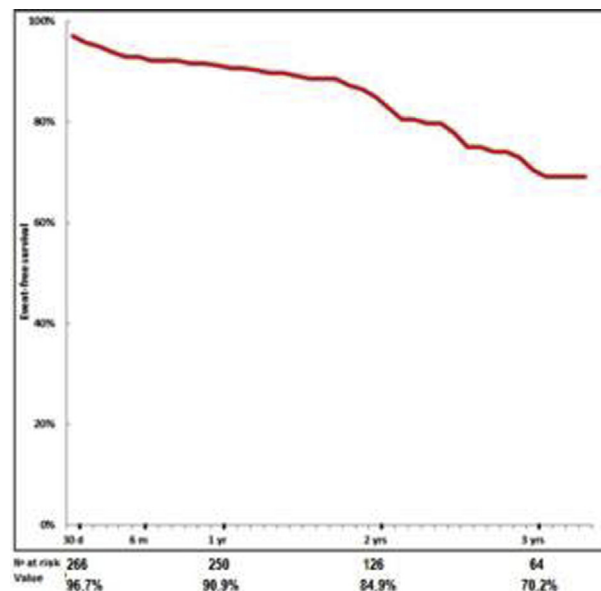
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**Background:** Transcatheter aortic valve implantation is the contemporary treatment of choice for high/prohibitive surgical risk patients with severe aortic stenosis.

**Methods:** Outcomes of consecutive 275 (61% female) severe aortic stenosis patients, treated with TAVI and followed up to 3 years (mean 702 days), were analyzed and reported according to the Valve Academic Research Consortium 2 definitions. The primary end point was death from any cause.

**Results:** This patient group (60% women) was characterized by advanced age (mean  $81.7 \pm 6.8$ ), high mean log-EuroScore =  $19.1 \pm 12$  and STS score =  $8.1 \pm 5$ . The Medtronic-CoreValve® device was utilized in 195 (71%) and the Edwards-Sapien® device in 80 (29%) of patients. The trans-femoral, trans-axillary, trans-apical,

trans-aortic and retroperitoneal route were used in 224, 20, 29, 1 and 1 patients; respectively. Procedural success was 97.1%. One month, 1 year, 2 and 3 years survival rates were 97%, 91%, 85% and 70%; respectively. Peri-procedural/in-hospital stroke was diagnosed in 9 (3.2%) patients. Permanent pacemaker was required in 40 (14.5%) patients: (36 cases in CoreValve and 4 in Sapien valves). Significant paravalvular leak ( $\geq$  moderate) was noted in 22 (8%) patients. After the procedure, mean valve gradients decreased from  $51.2 \pm 16$  to  $8.1 \pm 7$  ( $p < 0.001$ ). Symptomatic improvement was evident during follow up, having 98% of patients in NYHA-FC I or II.



**Conclusions:** The current report signifies that catheter-based treatment of mostly elderly patients with severe aortic stenosis is feasible, safe and associated with satisfactory long-term outcomes.

## TCT-758

### Hemodynamic Changes After Transcatheter Aortic Valve Implantation (TAVI) Significantly Influence Renal Function Thereby Impacting On Mortality

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**Background:** Acute kidney injury (AKI) is a serious complication after transcatheter aortic valve implantation (TAVI) and patients with preexisting renal impairment seem to be especially prone to AKI. Very few data exist about the impact of invasive hemodynamics on the occurrence of AKI after TAVI. The objectives of the study were (i) to determine the incidence and predictive factors for AKI with emphasis on invasive hemodynamics, and (ii) to examine short-and longterm outcome of these patients.

**Methods:** A total of 540 patients (mean age:  $80.2 \pm 7.1$ , logES:  $24.5 \pm 17.9\%$ ) undergoing TAVI were included in the study. Patients were divided into three groups according to their glomerular filtration rate (GFR) before TAVI (A: normal renal function i.e.  $\text{GFR} \geq 60 \text{ ml/min}$ ; B: impaired renal function i.e.  $\text{GFR} 30-59 \text{ ml/min}$ ; C: severe impaired renal function i.e.  $\text{GFR} < 30 \text{ ml/min}$ ). Renal function and survival were recorded over 12 months.

**Results:** Overall 30-day mortality was 10.2 % and 12-month mortality was 21.5%. Subgroup analysis showed significant differences between the groups with regard to 30-day-mortality (A: 5.4%, B: 9.0%, C: 25.0%) and 12-month mortality (A: 15.0%, B: 32.0%, C: 49%). AKI occurred in 30 patients (5.6%), of which the majority were patients of group B (16 patients). 30-day-mortality of patients with AKI was 53.3% (16 patients) and 12-month-mortality was 73.3% (22 patients). Systemic arterial pressures were significantly higher before and after TAVI in patients without AKI compared to patients with AKI, whereas preprocedural and postprocedural pulmonary and right atrial pressures did not differ between both groups. Predictive factors for

AKI comprised among others non-transfemoral access, anemia, high EURO Score and the absence of an increase in cardiac output (CO) after TAVI (AKI vs. non-AKI  $\Delta$ CO:  $0.2 \pm 8.6\%$  vs.  $7.2 \pm 26.5\%$ ,  $p < 0.0001$ ).

**Conclusions:** Preprocedural renal dysfunction has a prominent impact on mortality after TAVI. In addition, the occurrence of AKI after TAVI carries an even worse prognosis. In this regard, the maintenance of a sufficient blood pressure and an increase of cardiac output after TAVI seem to be protective against renal impairment.

## TCT-759

### Early Detection of Acute Kidney Injury Post Transcatheter Aortic Valve Replacement By a Novel Renal Biomarker

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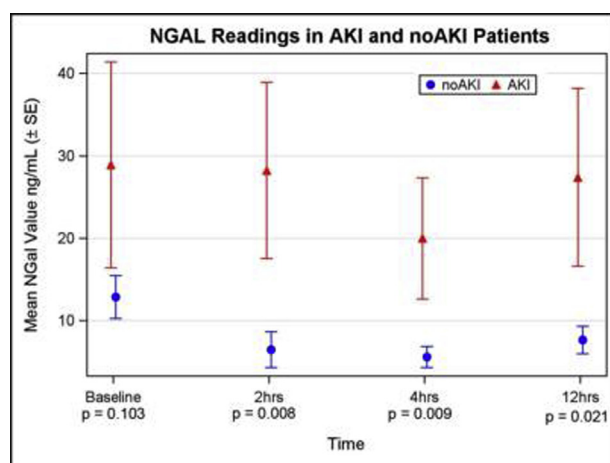
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**Background:** Neutrophil gelatinase-associated lipocalin (NGAL) is a novel biomarker associated with acute kidney injury (AKI) after cardiac procedures. NGAL allows earlier detection of AKI than serum creatinine (SCr) level but has not been evaluated post transcatheter aortic valve replacement (TAVR).

**Methods:** From 6/2012-5/2013, we enrolled 66 patients undergoing TAVR in this single-center pilot study. Urinary NGAL was measured at baseline, 2, 4, and 12 hours post op. Demographic, procedural features, and SCr until discharge were measured. The trend of NGAL post TAVR and the association of increased NGAL with AKI as per VARC-2 criteria was assessed.

**Results:** Twenty-two patients (33.3%) developed AKI postoperatively (Stage 1, 63.6%; Stage 2, 22.7%; Stage 3, 13.6%). There was no significant difference in baseline SCr, eGFR, or contrast dye volume between patients who developed AKI and those who did not but AKI patients had a significantly smaller aortic valve area. There was a significantly higher level of NGAL in patients with AKI versus those without AKI seen at 2, 4 and 12 hours post procedure (Figure), with the peak at 2 hours. After adjusting for gender, age, diabetes, TAVR type, and BMI; NGAL was significantly predictive of AKI at baseline (OR = 1.019 (95% CI 1.001 – 1.037,  $p=0.034$ ) and at each post op measurement.

**Conclusions:** NGAL was significantly elevated in patients who develop AKI both pre TAVR and post TAVR as early as 2 hours post procedure in this pilot study. This biomarker may assist in better determining patients at risk for and earlier detection and management of this frequent complication.



## TCT-760

### Treatment of Acquired von Willebrand Syndrome in Aortic Stenosis with Transcatheter Aortic Valve Replacement (TAVR)

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**Background:** An association between the acquired von Willebrand syndrome (aVWS) and valvular aortic stenosis (AVS) has been demonstrated in the past. While the extend of von Willebrand factor (aVWF) deficiency is related to the severity of AVS, surgical valve replacement (SAVR) can lead to factor recovery. Prevalence and course of the aVWS in patients treated with TAVR though has not yet been described comprehensively. Thus, we investigated the prevalence of the aVWS in patients undergoing TAVR and the impact on the underlying factor variances.

**Methods:** 104 consecutive patients (age:  $81.0 \pm 13.0$  years; logEUROscore  $22.9 \pm 18.5\%$ ) underwent TAVR at our institution. Comprehensive hemostaseologic testing was performed prior to and up to one week after TAVR. Transvalvular hemodynamics and right heart catheterisation as well as bleeding episodes were recorded and analyzed with descriptive statistics.

**Results:** Baseline prevalence of an aVWS was 41% with an average densitometric high-molecular-weight multimer (HMW-MM) count of  $16.6 \pm 3.5\%$ . Pressure gradients correlated significantly with the extent of high-molecular-weight multimer (HMW-MM) deficiency ( $r = -0.63$  [ $P < 0.0001$ ]). While in the past it has been shown to be vice-versa for SAVR, the necessity of blood transfusions was higher in our control-group1. Following valve implantation, HMW-MM increased proportional to the drop in mean pressure gradient and normalized within a week in 97% of the patients with prior aVWS.

**Conclusions:** We describe a significant prevalence of aVWS in patients undergoing TAVR. Since severe factor deficiency can lead to significant bleeding during SAVR, TAVR should be taken into consideration as a first line treatment for patients with AVS and concomitant aVWS.

## TCT-761

### Balloon-Expandable Transcatheter Aortic Valves Can Be Effectively And Safely Implanted Transfemorally Without Balloon Valvuloplasty

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**Background:** Balloon aortic valvuloplasty (BAV) has traditionally been part of the transcatheter aortic valve implantation (TAVI) procedure using balloon expandable valves. However, the benefit of this is unknown. We aimed to evaluate procedural success and safety in patients who underwent TAVI with and without BAV.

**Methods:** We retrospectively evaluated all TAVIs performed for predominant aortic stenosis using the balloon-expandable Edwards Sapien XT and Sapien 3 devices from March 2012 to April 2014. BAV was routinely performed only until May 2013. We assessed Valve Academic Research Consortium (VARC)-2 defined device success and safety; differences in procedure and fluoroscopy times and differences in embolic load based on transcranial Doppler (TCD). Categorical variables were analyzed using the Fisher exact test and continuous variables by the unpaired T-test on SPSS v21.

**Results:** 61 patients underwent BAV (Group 1) and 52 patients had no BAV (Group 2). There was no difference ( $p > 0.05$ ) in the rate of device success, specifically successful valve deployment (98.3% in Group 1 and 96.1% in Group 2), rate of post-deployment balloon dilatation (3.4% in Group 1 and 4.0% in Group 2) or incidence of moderate or severe aortic regurgitation (4.9% in Group 1 and 5.8% in Group 2). There were no differences in procedure safety (50.8% VARC-2 defined major and minor complications in Group 1 and 34.6% in Group 2,  $p=0.15$ ). In one case there was difficulty in crossing the valve without BAV, partial inflation of the distal balloon tip within the TAVI valve enabled crossing of the native aortic valve without subsequent deployment problems. There was a reduction in total fluoroscopic time in Group 2 vs Group 1 (13.2 vs 17.3 mins,  $p=0.006$ ), but no significant difference in total procedure time (112 vs 119 mins,  $p=0.21$ ). There were no differences between the 2 groups in terms of number of solid, gaseous or total emboli on TCD (all  $p > 0.05$ ).

**Conclusions:** Balloon-expandable TAVI valves can be implanted transfemorally without BAV, without a reduction in VARC-2 defined success or safety. Without performing a BAV there is a significant reduction in the fluoroscopic time. There is no difference in the rate of embolization on TCD.

## TCT-762

### Transcatheter Aortic Valve Implantation: A Single Center Comparison between Medtronic CoreValve and Edward SAPIEN Bioprostheses

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**Background:** Transcatheter aortic valve implantation (TAVI) is the new standard of care for inoperable patients with severe aortic stenosis and an alternative to surgical